EXHIBIT

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Interim report mesh explants pelvic floor repair April 2008

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Until April 2008 100 different explanted mesh samples from different manufacturers were evaluated histologically in the Düren Institute of Pathology by Prof. Klosterhalfen.

1. Most serious complication following mesh implantation in pelvic floor was mesh erosion in 80 to 90% of the cases. Mesh erosion is in nearly 100% combined with secondary mesh/surgical site infection SSI. Developing mesh ulceration follows this infection.
2. Primary mesh/surgical site infections are rare in pelvic floor implantations.
3. All meshes without exception induce typical foreign body tissue reaction known from mesh implants in hernia surgery.
4. Foreign body tissue reaction FBR induces fibrosis in the mesh implant area, i.e. severe FBR is associated with severe fibrosis.
5. Severe fibrotic tissue reaction is often associated with degenerative calcification.
6. For pelvic floor repair mostly small porous and heavy weight meshes or small porous and multi-filamentous meshes are used.
7. These meshes named under 6. induce severe foreign body tissue reaction and severe fibrosis.
8. Mesh erosions are always associated with severe fibrosis.
9. Neuromas and neuronal proliferations are found often in the periphery of pelvic floor mesh implants.
10. Neuromas and neuronal proliferations induce chronic pain.
11. Severe fibrosis is found in folded mesh implants with double layers. Mesh shrinkage and folding is obvious in pelvic floor repair.

Summary:

Foreign body tissue reaction followed by secondary fibrosis seems to play a special role in pelvic floor repair. This is important, because soft tissue coverage is thin in pelvic floor repair. Fibrosis and folding in this area are inducing mesh erosions and ulcerations.

(Translation: April 7th, 2008; Jörg L. Holste, DVM, PhD; Senior Research Fellow)

Intermediate Report – Prolapse Mesh Explants 6/2009

Up to June 2009, 172 mesh explants from different manufacturers were histologically examined and the results analyzed. It emerged that the different products from the different manufacturers presented a very consistent complications profile.

1. The main complication for all mesh products was erosion, which was found in 80-90% of the explants. The erosion was associated with a secondary related infection and formation of a florid mesh-related ulcer in almost 100% of cases.
2. Primary infections as the reason for explantation were usually rather rare.
3. Without exception all meshes exhibited a typical foreign body reaction (FBR), which is also known to occur with the meshes used in hernial surgery.
4. The FBR is basically responsible for fibrosis at the implant site, i.e. a strong FBR is associated with marked fibrosis.
5. Strong fibrosis is associated with degradation-calcification to a greater than average extent.
6. Small and medium pore, heavy and medium weight, and small-pore multifilament mesh types dominate the current market for prolapse repair mesh devices and therefore were the most commonly explanted types.
7. All the mesh types referred to in item 6 above basically precipitate a strong FBR and consequent scarlike fibrosis.
8. Strong fibrosis almost always leads to wrinkle formation in the mesh due to increased mesh shrinkage.
9. Shrinkage leading to wrinkle formation is almost always detectable in the area of the erosion.
10. Neuromas and pseudoneuromas are frequently found at above-average rates along the fibrosis margins.
11. Neuromas and pseudoneuromas are frequently associated with chronic pain at above-average rates.
12. Light-weight, large-pore mesh types demonstrate smaller FBR, just as in the case of hernias. Smaller FBRs produce less fibrosis in this case also.
13. The group of explants of light-weight, large-pore mesh types is small (n = 13), and therefore a definitive statement cannot yet be made.
14. The database also includes 55 collagen patch/mesh devices. These sometimes precipitate a strong FBR (e.g. Pelvicol) and fibrosis. Collagen patches also exhibit secondary infections with erosion.*
15. Collagen nonwoven materials are quickly absorbed within a few weeks and therefore demonstrate more relapses.
16. Complications such as feeling the presence of a FB or pain are not observed more frequently with collagen patches than with polypropylene (PP) implants.

In summary, therefore, FBRs and secondary fibrosis seem to play a significant role in prolapse repair.

This gains in importance seeing that the repair involves the introduction of the mesh into an anatomic area where the tissue layers are only millimeters thick and wide. Strong

fibrosis in such areas inevitably leads to mechanical irritation, particularly when wrinkling occurs, and should be seen as the basic cause of mesh-induced erosion and ulceration.

Infection is commonly observed following erosion in the vaginal mucosa. Primary infection without mucosal erosion is seldom found.

Neuromas and pseudoneuromas with increased perineural fibrosis are frequent and explain the majority of cases where explantation must be performed to alleviate persistent and chronic pain.

Reducing the implant surface produces a beneficial effect on the FBR and fibrosis. The implant remains more flexible and neural involvement is less common. A definitive analysis is not yet feasible because of the small group size.

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Prof. Bernd Klosterhalfen, MD *[? name partly illegible]*

*It is possible that an error was made between Fliese and Vlies here, since the singular word Fliese is used with a pleural verb (…"weisen…") and in association with another plural noun ("/Netze"). The meaning is not affected; see the glossary for further details.